PATENT

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In the Matter of the: Application of	Jeffrey C. Cerier	
Serial No.	: 10/677,633	Confirmation No.: 4181
Filed	: October 2, 2003	Group Art Unit: 3773
Entitled	:TISSUE FIXATION DEVICES AND METHODS OF FIXING TISSUE	Examiner: J. W. Woo
Docket No.	: 100873-283 (END6430USCIP5)	

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APPEAL BRIEF PURSUANT TO 37 C.F.R. § 41.37

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I. REAL PARTY IN INTEREST

The real party in interest is Ethicon Endo-Surgery, Inc., a Johnson & Johnson company. Ethicon Endo-Surgery, Inc. derives its rights in this application by virtue of an assignment of the application by the inventors to NDO Surgical, Inc., recorded at Reel 018886, Frame 0319. NDO Surgical, Inc. assigned its rights in the present application to Ethicon Endo-Surgery, Inc. as indicated in the Patent Assignment submitted to the U.S. Patent Trademark Office on June 10, 2009, attached in Appendix B.

II. RELATED APPEALS AND INTERFERENCES

None.

III. STATUS OF CLAIMS

Claims 7, 8, 10-28, and 41-44 are currently pending in the present application, Serial Number 10/677,633. According to the final Office Action dated August 12, 2009 ("Office Action"), claims 11-13, 15, and 22-26 are rejected pursuant to 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 4,669,473 ("Richards"), claims 7-10, 18-21, and 41-44 are rejected pursuant to 35 U.S.C. § 103(a) as being obvious over Richards in view of U.S. Patent No. 5,219,359 ("McQuilkin"), and claims 16, 17, 27, and 28 are rejected pursuant to 35 U.S.C. § 103(a) as being obvious over Richards in view of U.S. Patent No. 5,845,645 ("Bonutti"). Claims 1-6 and 29-40 have been canceled.

Appellant presumes that the Examiner intended to also reject claim 14 pursuant to 35 U.S.C. §103(a) as being unpatentable over Richards at least because claim 14 is listed as rejected in the Office Action Summary and because the limitations of claim 14 are addressed in discussing the rejection of claims 11-13, 15, and 22-26 on page 3 of the Office Action.

Accordingly, the rejections of claims 7, 8, 10-28, and 41-44 are appealed.

IV. STATUS OF AMENDMENTS

Appellant did not submit any claim amendments subsequent to the Office Action.

A copy of the pending claims is attached as Appendix A.

V. SUMMARY OF CLAIMED SUBJECT MATTER

Independent claim 7 recites a tissue fixation device. *See, e.g.,* p. 23, lines 2-7 (Abstract). An exemplary tissue fixation device (10') according to the invention is illustrated in Figures 1-4 and includes a suture (12), a first bioimplantable pledget (24), a second bioimplantable pledget (34), and a first bioimplantable securing element (14) connected to a portion (18) of the suture (12). *See, e.g.,* p.5, lines 3-6; p. 7, lines 11-12; p. 8, lines 5-10 (para. [0030]; [0036]; [0038]). The first bioimplantable pledget (24) has at least one through hole (32) formed therein having a minimum diameter greater than a maximum diameter of the suture (12). *See, e.g.,* p. 7, lines 13-15 (para. [0036]). A first portion of the suture (12) passes through the at least one through hole (32) in the first pledget (24), and a second portion of the suture (12) is configured to inhibit the second portion from passing through the at least one through hole (32) in the first pledget (24). *See, e.g.,* p. 5, lines 4-23 (para. [0030]-[0031]). The second bioimplantable pledget (34) has at least one through hole (36) formed therein, and the first pledget (24) is spaced apart from the second pledget (34) to receive tissue (36) therebetween when the tissue fixation device (10') is deployed. *See, e.g.,* p. 8, lines 5-10 and 25-29 (para. [0038]; [0041]). The first bioimplantable securing element (14) is rotatable from a first orientation in which the securing element (14) is oriented at least substantially parallel to the at least one through hole (32, 36) formed in the first pledget (24) and the second pledget (34), to a second orientation in which the securing element (14) is oriented at least substantially perpendicular to the at least one through hole (36) in the second pledget (34). *See, e.g.,* p. 6, line 12 to p. 7, line 10 (para. [0034]-[0035]). The suture (12), the first and second pledgets (24, 34), and the first securing element (14) are effective to fix adjacent layers of living tissue (36). *See, e.g.,* p. 1, line 25, to p. 2, line 5 (para. [0004]).

Dependent claim 8 depends from claim 7 and recites a second suture (12a) and a second bioimplantable securing element (16) connected to a portion of the second suture (12a). *See, e.g.,* Figures 1-3 and 6; p. 5, lines 3-4; p. 9, lines 17-18 (para. [0030]; [0042]).

Dependent claim 9 depends from claim 8, which depends from claim 7, and recites that a first portion of the second suture (12a) passes through a second through hole (32) in the first pledget (24) and a second portion (K) of the suture (12a) is configured to inhibit the second portion (K) of the suture (12a) from passing through the second through hole (32) in the first pledget (24). *See, e.g.,* Figure 7; p. 9, lines 19-25 (para. [0043]).

Independent claim 11 recites a tissue fixation device. *See, e.g.,* p. 23, lines 2-7 (Abstract). An exemplary tissue fixation device according to the invention is illustrated in Figures 1-4, 9, and 10 and includes a suture (12) suitable for in vivo placement in a human body, a first biocompatible securing element (14) connected to a first portion (18) of the suture (12), and a second biocompatible securing element (16) connected to a second portion (20) of the suture (12). *See, e.g.,* p. 1, line 25, to p. 2, line 5; p. 5, lines 3-6 (para. [0004]; [0030]). Each of the first and second securing elements (14, 16) are rotatable from a first position during deployment of the tissue fixation device that is suitable for each securing element (14, 16) to pass through a respective hole formed in human or animal tissue (36) to a second position substantially perpendicular to the first position when the tissue fixation device is deployed that inhibits each securing element (14, 16) from passing through the respective hole formed in the tissue (36). *See, e.g.,* p. 6, line 12 to p. 7, line 10 (para. [0034]-[0035]). The tissue fixation device also includes a deployment instrument (46) having first and second tubes (54, 56) configured to deliver the first and second securing elements(14, 16) in the first position through the tubes (54, 56) and through the respective hole formed in the tissue (36). *See, e.g.,* p. 10, lines 3-30 (para. [0046]-[0049]).

Dependent claim 15 depends from claim 13, which depends from claim 12, which depends from claim 11, and recites that the portions of the suture (12) coupled together are coupled by welding. *See, e.g.,* p. 10, lines 16-23 (para. [0031]).

Dependent claim 23 depends from claim 11 and recites that the first securing element (14) and the second securing element (16) are oriented at least substantially perpendicular to the holes in the tissue (36) in the second position. *See, e.g.,* p. 6, lines 21-24 (para. [0035]).

Dependent claim 27 depends from claim 11 and recites that the suture (12) is endless. *See, e.g.,* p. 5, line 17 (para. [0031]).

Dependent claim 28 depends from claim 11 and recites that the suture (12) forms a closed loop. *See, e.g.,* p. 5, lines 16-23 (para. [0031]).

Independent claim 41 recites a tissue fixation device (10'). *See, e.g.,* p. 23, lines 2-7 (Abstract). An exemplary tissue fixation device (10') according to the invention is illustrated in

Figures 1-4 and includes a suture (12), a first bioimplantable pledget (24) having a plurality of through holes (22) formed therein, a second bioimplantable pledget (34) having a plurality of through holes (22) formed therein, a first bioimplantable securing element (14) coupled to the suture (12), and a second bioimplantable securing element (16) coupled to the suture (12). *See, e.g.,* p.5, lines 3-8; p. 7, lines 11-12; p. 8, lines 5-10 (para. [0030]; [0036]; [0038]). The suture (12) passes through the through holes (22) in the first pledget (24). *See, e.g.,* p. 5, lines 4-23 (para. [0030]-[0031]). The first pledget (24) is spaced apart from the second pledget (34) to receive tissue (36) therebetween when the tissue fixation device (10') is deployed. *See, e.g.,* p. 8, lines 25-29 (para. [0041]). The first bioimplantable securing element (14) and the second bioimplantable securing element (16) each have a sharp tip and a proximal end configured for removable attachment to an instrument (46). *See, e.g.,* Figures 9 and 10; p. 7, lines 25-29; p. 8, lines 11-14; p. 10, lines 3-30 (para. [0037]; [0039]; [0046]-[0049]). The suture (12), the first and second pledgets (24, 34), and the first and second securing elements (14, 16) are effective to fix adjacent layers of living tissue (36). *See, e.g.,* p. 1, line 25, to p. 2, line 5 (para. [0004]).

Support for the claimed subject matter is provided parenthetically to guide the Board in its understanding of the claimed subject matter. However, support for the claims is provided throughout the specification and is not necessarily limited to the specific paragraphs, pages, and line numbers provided in this concise summary.

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

A. Whether the Examiner improperly rejected claims 11-13, 15, and 22-26 pursuant to 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 4,669,473 ("Richards").

B. Whether the Examiner improperly rejected claims 7-10, 18-21, and 41-44 pursuant to 35 U.S.C. § 103(a) as being obvious over Richards in view of U.S. Patent No. 5,219,359 ("McQuilkin").

C. Whether the Examiner improperly rejected claims 16, 17, 27, and 28 pursuant to 35 U.S.C. § 103(a) as being obvious over Richards in view of U.S. Patent No. 5,845,645 ("Bonutti").

VII. ARGUMENT

The Examiner relies on Richards as the primary reference for all claim rejections. The Examiner admits that Richards fails to disclose a number of elements required by the claims and thus relies on various secondary references to manufacture rejections of the claims. However, as discussed further below, there is no legal basis upon which the reference combinations and modifications proposed by the examiner can be made. The claims' subject matter is distinctly different from what is described in Richards. Short of random modifications of Richards, which are indicative of hindsight, the prior art does not teach or suggest the claimed invention.

Below we first discuss the scope and content of Richards because it provides the basis for all rejections. We then address each rejection in the order in which they appear in the Office Action, discussing secondary references as appropriate for the rejection.

A. The Scope and Content of Richards

The Office Action rejects each of the pending claims over Richards alone or in combination with one additional reference. Richards generally discloses a "surgical fastener having at least one head portion and a filament portion arranged in a T configuration, wherein at least one end of the said at least one head portion is sharply pointed, so that when that head portion is implanted in body tissue, the head portion will attach itself securely to the tissue and will remain there despite the application of a substantial pulling force on the filament portion." Richards, Abstract. The Examiner relies on one embodiment of a surgical fastener illustrated in Figures 10-14 in rejecting independent claim 11 and on another embodiment of a surgical fastener illustrated in Figures 8 and 9 in rejecting independent claims 7 and 41, so we discuss these embodiments of Richards in more detail. Appellant focuses on these embodiments although the arguments herein similarly apply to other embodiments in Richards.

Richards discloses one embodiment of a surgical fastener (305) having two fastener heads (315, 316) with a filament (310) extending therebetween, as shown in Figure 10, reproduced below. The fastener heads (315, 316) "are formed integral with filament 310 so that they normally extend at a right angle to the adjoining lengths of the filament." Richards, col. 6, lines 27-31. During deployment of the fastener (305) to secure tissue, the fastener heads (315, 316) are each in a first position bent ninety degrees from the normal position illustrated in Figure

10 and delivered into adjacent tissues (500, 505) through a sheath (405) of a deployment tool (400), as shown in Figures 11 and 12, reproduced below. *Id.*, col. 4, lines 19-33; col. 7, line 65 to col. 8, line 35. Following deployment through holes in the tissues (500, 505), as shown in Figure 13, reproduced below, "the fastener's heads 315 and 316 will dig into the surrounding tissue as the heads attempt to resume their normal position substantially perpendicular to the adjoining filament 310." *Id.*, col. 8, lines 53-56. The tool (400) is then removed from the tissues (500, 505) such that the fastener (305) attaches the tissues (500, 505) together with the fastener heads (315, 316) firmly implanted therein and the filament (310) positioned outside the tissues (500, 505) and connecting the fastener heads (315, 316) together. *Id.*, col. 9, lines 10-16.

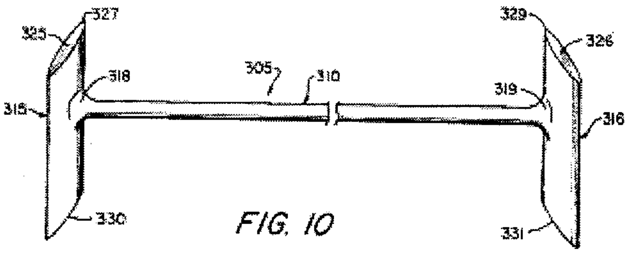

FIG. 10

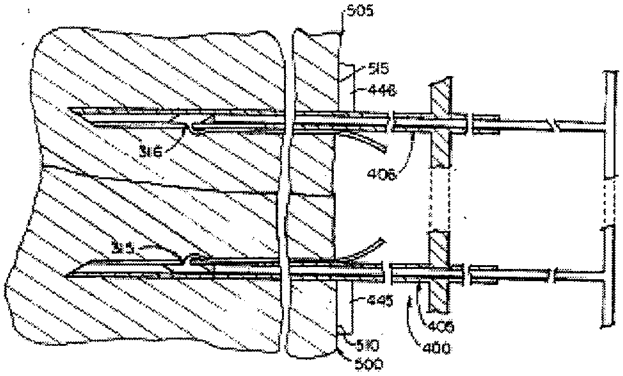

FIG. 12

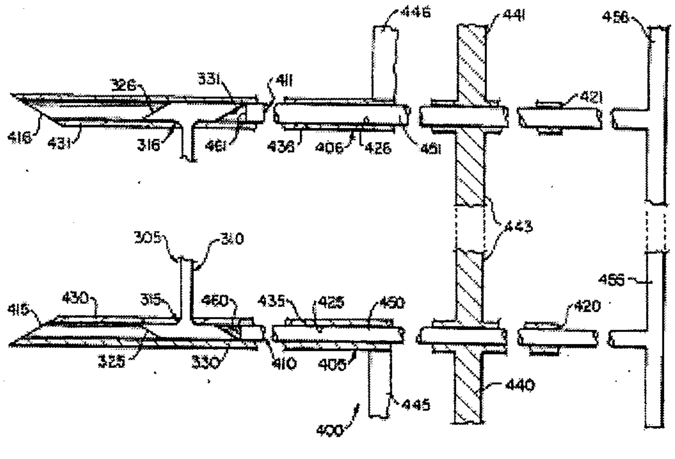

FIG. 11

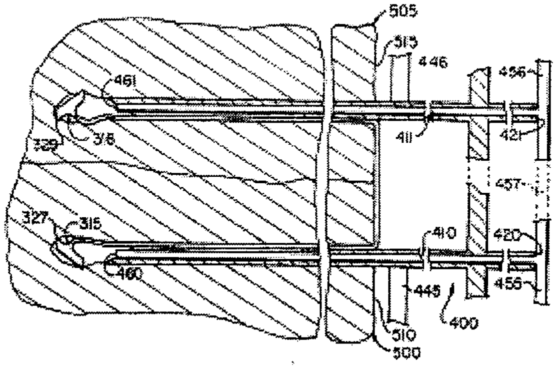

FIG. 13

In another embodiment disclosed in Richards, shown below in Figures 8 and 9, a surgical fastener (5B) has only one fastener head (15B) and has a plurality of ribs (35B) formed on its filament (10B). The fastener (5B) secures adjacent tissues (200B, 210B) similar to that described above regarding the first surgical fastener (305), except that a washer (40B) is used to secure the fastener (5B) to the tissues (200B, 210B). The washer (40B) is slid over the filament (10B) and held thereon by one of the ribs (35B), which are each conically shaped to allow movement of the washer (40B) in a direction toward the fastener head (15B) while preventing movement in an opposite direction. *Id.* at col. 6, lines 9-13. Thus, as shown in Figure 9, the fastener head (15B) is embedded within one of the tissues (200B) with the washer (40B) abutting an outside surface of the other tissue (210B)to hold the fastener (5B) in place attaching the adjacent tissues (200B, 210B) together.

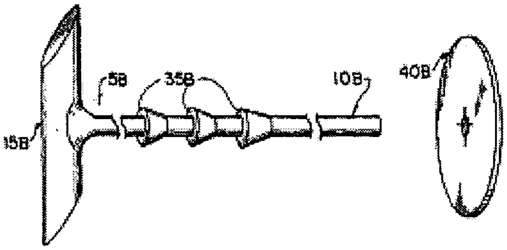

FIG. 8

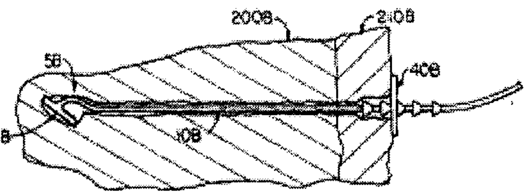

FIG. 9

B. Rejection of Claims 11-15 and 22-26 Pursuant to 35 U.S.C. §103(a) Over Richards

Claims 11-13, 15, and 22-26 are finally rejected pursuant to 35 U.S.C. §103(a) as being unpatentable over Richards. As mentioned above, Appellant presumes that the Examiner intended to also reject claim 14 pursuant to 35 U.S.C. §103(a) as being unpatentable over Richards at least because claim 14 is listed as rejected in the Office Action Summary and the limitations of claim 14 are addressed on page 3 of the Office Action.

1. The Examiner's Rejection of Independent Claim 11

The Examiner argues that Richards discloses the claimed invention as recited in claim 11, at least in Figures 10-14 and at col. 6, line 20 to col. 9, line 23. However, the Examiner admits that

> Richards et al. do not specifically disclose that the second biocompatible securing element is rotatable from a first position to a second position substantially perpendicular to the first position when the tissue fixation device is deployed. Nevertheless, Richards et al. teach, at least in col. 4, line 55 to col. 5, line 6 and col. 5, lines 43-49; that a securing element not only tends to rotate from a first position to a second

> position substantially perpendicular to the first position, the securing element, when tugged upon during deployment in tissue, "tends to set the fastener even deeper into the tissue" (i.e., the securing element, when deployed in tissue, is able to be rotated beyond the nearly-perpendicular angle shown in the figures). In other words, the securing element is indeed rotatable or capable of rotating from first position to second position substantially perpendicular to the first position, when the device is deployed in tissue. In any case, it would be obvious to one having ordinary skill in the art at the time the invention was made, in view of this teaching, to rotate or configure the securing element of Richards et al., so that it is moved or movable from a first position to a second position substantially perpendicular to the first position. Such a modification would ensure firm anchorage of the securing element in tissue, i.e., when the fastener is set deeply in tissue.

Office Action, p. 3-4.

2. Claims 11-14, 22, and 24-26 are Patentable Over Richards

Independent claim 11 recites a tissue fixation device including a suture suitable for in vivo placement in a human or animal body, a first biocompatible securing element connected to a first portion of the suture, and a second biocompatible securing element connected to a second portion of the suture. Each of the first and second securing elements are rotatable from a first position during deployment of the tissue fixation device that is suitable for each securing element to pass through a respective hole formed in human or animal tissue to a second position substantially perpendicular to the first position when the tissue fixation device is deployed that inhibits each securing element from passing through the respective hole formed in the human or animal tissue. The tissue fixation device also includes a deployment instrument having first and second tubes configured to deliver the first and second securing elements in the first position through the tubes and through the respective hole formed in said tissue.

As mentioned above, the Examiner agrees that Richards does not disclose that "the first and second securing element [are] rotatable from a first position during deployment of the tissue fixation device ... to a second position substantially perpendicular to the first position when the tissue fixation device is deployed" as required by claim 11. Because of this deficiency, the Examiner proposes to modify Richards to "rotate or configure the securing element of Richards et al., so that it is moved or movable from a first position to a second position substantially perpendicular to the first position." Office Action, p. 3-4.

This modification is not possible because there is no motivation for a person of ordinary skill in the art to so reconstruct Richards as proposed by the Examiner because (i) there is no advantage or beneficial result to the proposed modification, (ii) modifying Richards would require a substantial reconstruction and redesign of Richards, and (iii) the Examiner's rejection improperly relies on hindsight reasoning. Independent claim 11 thus distinguishes over Richards for all of these reasons, which are discussed below in more detail.

(a) The Examiner Mischaracterizes Richards

At the outset, Appellant notes that the Examiner's rejection is based on a mischaracterization of Richards, thereby failing to establish a prima facie case of obviousness. In presenting the rejection of claim 11 on page 3 of the Office Action the Examiner states that Richards does not specifically disclose that "the first and second securing element [are] rotatable from a first position during deployment of the tissue fixation device ... to a second position substantially perpendicular to the first position when the tissue fixation device is deployed" as required by claim 11. Subsequently, in discussing how it would have been obvious to modify Richards to have such securing element, the Examiner states that because pulling on the filament in Richards with the fastener head within tissue "'tends to set the fastener even deeper into the tissue,' ... the securing element *is indeed rotatable or capable of rotating from first position to second position substantially perpendicular to the first position*, when deployed in tissue." Office Action, p 3-4 (quoting Richards, col. 5, lines 46-49). (Emphasis added.) The Examiner cannot simultaneously assert that Richards fails to disclose a required limitation of claim 11 and that Richards does disclose that same required limitation.

Richards in fact discloses that the heads (315, 316) of the fastener (305) do *not* and *cannot* rotate to a position substantially perpendicular to their normal position when deployed. The heads (315, 316) do not move and are not capable of moving to a second position substantially perpendicular to the first position but instead only *attempt* to do so. Richards plainly explains that the heads (315, 316) "return only a fraction of the way back to its original perpendicular position." Richards, col. 8, line 57 to col. 9, line 5. The heads (315, 316) do not and cannot return to their normal, substantially perpendicular position when deployed for a variety of reasons identified by Richards, including "the fact that the holes formed in the tissue by the retreating tool 400 are significantly smaller in diameter than the length of fastener heads 315 and 316 (i.e., the distance between angled surfaces 325 and 330 and angled surfaces 326 and 331)" and "the fact that those holes will tend to close inwardly under the pressure of the surrounding resilient tissue." *Id.* Thus, it is clear that the fastener heads (315, 316) are *not* rotatable from a first position to a second position that is substantially perpendicular to the first position when the device is deployed in tissue. The fastener heads (315, 316) are not even capable of doing so because their sharply pointed ends engage tissue to hold the heads (315, 316) and the fastener (305) in place as the heads (315, 316) merely *attempt* to move to the normal position.

Richards specifically mentions that the sharply pointed ends of the heads (315, 316) are specially designed to effectively secure the fastener (305) in tissue by "penetrate[ing] sufficiently into the walls of the tissue so that the fastener will be anchored to the body tissue." *Id.*, col. 5, lines 3-6. Richards specifically identifies these pointed ends of the heads (315, 316) as "an important feature of the invention" and states that with such pointed ends, the heads (315, 316) "will be able to engage the tissue and anchor the fastener in the manner just described." *Id.*, col. 5, lines 7-11.

It is improper for the Examiner to fabricate a claim element in the Richards disclosure, namely by baldly asserting that "the securing element is indeed rotatable or capable of rotating from first position to second position substantially perpendicular to the first position, when the device is deployed in tissue." Office Action, p. 4. At best, Richards states that the fastener heads (315, 316) in Richards merely *attempt* to return to their normal position but are not able to do so. Not only is the Examiner's fabrication unsupported by the Richards disclosure, it is *inconsistent* with the disclosure. Even if the filament (310) is pulled after the fastener heads (315, 316) are inserted within tissue, Richards still only discloses that the fastener heads (315, 316) *attempt* to return to their normal position and that the pointed ends of the heads (315, 316) simply dig further into the tissue as the filament (310) is pulled, making any perpendicular orientation further unlikely. Richards, col. 5, lines 43-49. The fastener heads (315, 316) are simply incapable of functioning as recited in claim 11 even if one desired them to do so.

The Examiner also misrepresents the teaching of Richards on pages 3-4 of the Office Action with regard to the pulling of the fastener which "tends to set the fastener deeper into the tissue." *Id.* at col. 5, lines 43-49. The Examiner fails to address the first portion of the sentence discussing the pulling of the fastener, which states that "*on account of the angle at which the fastener's sharpened head is disposed in tissue*, pulling on the free end of the fastener tends to set the fastener even deeper in tissue." *Id.* Hence, Richards does not teach or suggest that pulling the filament (310) rotates the fastener heads (315, 316) in any way. Rather, because of the *non-perpendicular angle* at which the fastener heads (315, 316) are specifically disclosed to be oriented when securing tissue, pulling on the filament (310) digs the fastener heads' sharpened tips deeper into the tissue. Richards is very clear in multiple portions of the specification that the fastener heads (315, 316) do not return to their normal, perpendicular position in tissue, and it is only by mischaracterizing Richards that the Examiner is able to suggest otherwise. *See id.* at col. 4, line 45 to col. 5, line 6; col. 8, line 57 to col. 9, line 23; col. 10, lines 30-58.

(b) There Is No Motivation For A Person Of Ordinary Skill In The Art To Modify Richards As Proposed By The Examiner

The Examiner appears to be arguing that although Richards does not explicitly disclose that the fastener heads (315, 316) are rotatable from a first position to a second position substantially perpendicular to the first position when the tool (400) is deployed, it would be obvious to modify Richards so the heads (315, 316) rotate as required by claim 11 in light of Richards's teaching that pulling on the filament (310) sets the heads (315, 316) deeper into tissue. In other words, the Examiner is arguing that it would be obvious for a person of ordinary skill in the art to pull on the filament (310) until the heads (315, 316) rotate to their normal, perpendicular position. However, there is no motivation for a person of ordinary skill in the art to make such a modification.

(i) There Is No Advantage Or Beneficial Result To The Proposed Modification

The strongest rationale for combining references is a recognition that some advantage or expected beneficial result would be produced by the combination. MPEP §2144(II). Here, there is no advantage to or beneficial result in modifying Richards as suggested by the Examiner. As mentioned above, the Examiner asserts that modifying Richards "would ensure firm anchorage of the securing element in tissue, i.e., when the fastener is set deeply into the tissue." Office Action, p. 4. However, that result is not an advantage or beneficial result since it is exactly what Richards already achieves with its surgical fastener.

As mentioned above, Richards discloses that the heads (315, 316) of the fastener (305) do not rotate to a position substantially perpendicular to their normal position when deployed. The fastener (305) in Richards is nevertheless effective to fasten tissue as designed and as explicitly disclosed. There is absolutely no reason why a person having ordinary skill in the art would modify Richards as suggested by the Examiner to "ensure firm anchorage of the securing element in tissue" when the heads (315, 316) *already* firmly anchor the heads (315, 316) in tissue.

Furthermore, pulling on the filament (310) with sufficient tension to force both of the heads (315, 316) in an attempt to rotate them to their normal, perpendicular position would only serve to increase chances of unnecessarily damaging the tissue with the sharp ends of the heads (315, 316). A person of ordinary skill in the art would be loathe to attempt to force such rotation of the heads (315, 316) when they are particularly designed to anchor in tissue without so rotating and without application of such high tension, and such a person would undoubtedly recognize that the heads (315, 316) would not even achieve a perpendicular position. Thus, rather than providing an advantage or beneficial result, the Examiner's proposed modification risks harming the patient.

Accordingly, since Richards does not provide any teachings that would offer any beneficial result to modifying its surgical fastener as suggested by the Examiner, there is simply no advantage to so modify Richards. The modification is therefore not obvious, particularly in light of such a modification of Richards requiring a substantial reconstruction and redesign of Richards and such a modification of Richards being the result of impermissible hindsight reasoning.

(ii) Modifying Richards Would Require A Substantial Reconstruction And Redesign Of Richards

A prima facie case of obviousness is also not established if the "suggested combination of references would require a substantial reconstruction and redesign of the elements shown in [the primary reference] as well as a change in the basic principle under which the [primary reference] construction was designed to operate." MPEP §2143.01(VI) quoting *In re Ratti*, 270 F.2d 810, 813, 123 USPQ 349, 352 (CCPA 1959). Modifying Richards as suggested by the Examiner would require a substantial reconstruction and redesign of Richards, which further demonstrates the impropriety of the Examiner's rejections.

Modifying Richards as suggested by the Examiner such that the heads (315, 316) so rotate to a substantially perpendicular orientation when deployed in tissue would require a substantial redesign and reconstruction of Richards's surgical fastener (305). As discussed above, Richards fails to disclose securing elements that rotate from a first position to a second position that is substantially perpendicular to the first position. Instead, the fastener heads (315, 316) specifically do not do so. Thus, the fastener heads (315, 316) would have to somehow be modified to allow the heads (315, 316) to so rotate when the surgical fastener (305) is deployed as required by claim 11, despite no teaching or suggestion in Richards to do so. The Examiner does not provide any indication how a person of ordinary skill in the art could modify the device of Richards such that the fastener heads (315, 316) can rotate as required by claim 11, and Appellant cannot identify any way this could be accomplished, much less a way that does not require a substantial redesign and reconstruction.

Accordingly, the Examiner's proposed modification of Richards amounts to a substantial reconstruction and redesign of Richards's surgical fastener and thereby cannot establish obviousness of claim 11.

(iii) The Examiner's Rejection Improperly Relies On Hindsight Reasoning

As mentioned above, the only reason provided in the Office Action for modifying Richards such that the fastener heads (315, 316) rotate as required by claim 11 is that it would "ensure firm anchorage of the securing element in tissue." Office Action, p. 4. While Appellant does not disagree that Richards discloses a surgical fastener effective to securely anchor in tissue, the Examiner's reasoning behind the proposed modification is gleaned directly and only from Appellant's disclosure. This is the definition of hindsight being used to impermissibly formulate a rejection of the claims. That the Examiner, after having read Appellant's disclosure, can look at Richards and choose to modify Richards's fastener (305) does not bar patentability. *See In re Kotzab*, 217 F.3d 1365, 1371, 55 USPQ2d 1313, 1317 (Fed. Cir. 2000) (stating that the Examiner may not "use the claimed invention as an instruction manual or 'template' to piece together the teachings of the prior art so that the claimed invention is rendered obvious") (citations omitted).

To make a prima facie showing of obviousness of a claimed invention, the Examiner should "identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does. This is so because inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known." *KSR*, 127 S. Ct. at 1741; *see* MPEP §2141, §2143.01(IV). A factfinder should be aware, of course, of the distortion caused by hindsight bias and must be cautious of arguments reliant upon ex post reasoning. *See Graham v. John Deere Co.*, 383 U.S. 1, 36 (1966) (warning against a "temptation to read into the prior art the teachings of the invention in issue" and instructing courts to "'guard against slipping into the use of hindsight'".) *KSR*, 127 S. Ct. at 1742. Where no such explanation is given, as is the case here, improper use of hindsight can be inferred.

There is absolutely no reason why a person having ordinary skill in the art would modify Richards so that during deployment of the fastener (305) the heads (315, 316) rotate from a first position to a second position substantially perpendicular to the first position, absent use of Appellant's disclosure as a roadmap. Richards does not disclose that during deployment of the fastener (305) the heads (315, 316) rotate from a first position to a second, substantially perpendicular position, and a person having ordinary skill in the art would have no reason to add such a feature because Richards's fastener (305) is perfectly effective for securing tissue, as discussed above. Moreover, given that Richards specifically discloses that the heads (315, 316) do *not* move to a second, substantially perpendicular position and that the heads (315, 316) are perfectly effective for fastening tissue as disclosed therein, it would not have been obvious for a person of ordinary skill in the art to modify Richards as suggested by the Examiner.

Accordingly, for at least all of the aforementioned reasons, independent claim 11, as well as claims 12-14, 22, and 24-26 which depend therefrom, distinguish over Richards and represent allowable subject matter.

3. Claim 15 is Patentable Over Richards

Claim 15 ultimately depends from claim 11. Accordingly, claim 15 is not obvious over Richards for at least the same reasons that claim 11 is not obvious. Claim 15 is also not obvious over Richards for additional reasons.

Claim 15 depends from claim 13, which depends from claim 12, which depends from claim 11, and recites that the portions of the suture coupled together are coupled by welding. The Examiner relies on column 5, lines 50-55 and column 6, lines 20-22 as disclosing such a feature on p. 4 of the Office Action. The Examiner further argues that "claim 15 is construed as a product-by-process claim, and the product (suture) does not depend on the process of making it. The claimed product appears to be the same as the suture of Richards et al. Thus, the suture of Richards et al. is obvious over the claimed (welded) suture." Office Action, p. 4.

The Examiner's rejection is improper for at least two reasons. First, claims 15 is not a product-by-process claim. To be properly considered a product-by-process claim, a claim must "define the claimed product in terms of the process by which it is made." MPEP §2173.05(p) (citing *In re Luck,* 476 F.2d 650, 177 USPQ 523 (CCPA 1973); *In re Pilkington,* 411 F.2d 1345, 162 USPQ 145 (CCPA 1969); *In re Steppan*, 394 F.2d 1013, 156 USPQ 143 (CCPA 1967)); *see Abbott Laboratories v. Sandoz, Inc.*, 566 F.3d 1282, 1293 (Fed. Cir. 2009). Claim 15 does not define the claimed "suture" by a process in which it is made but rather recites a suture having portions coupled together by welding. At the very least, this recitation relays structure of physically welded suture. It is improper for the Examiner to ignore the requirements of a structural feature of the claimed invention, namely welded suture portions.

Second, even if claim 15 is considered a product-by-process as argued by the Examiner, Richards must disclose the same structure as in the claimed invention to render the claim obvious. "'[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.' *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted)" MPEP §2113. The filament (310) of Richards is not the same structure recited in claim 15 but merely formed by a different method. Instead, the filament (310) in Richards is simply a singular member that does not include any welded portions. Richards fails to disclose suture portions coupled together by welding. Indeed, Richards does not mention welding at all.

Accordingly, for at least all of the aforementioned reasons, dependent claim 15 distinguishes over Richards and represents allowable subject matter.

4. Claim 23 is Patentable Over Richards

Claim 23 depends from claim 11. Accordingly, claim 23 is not obvious over Richards for at least the same reasons that claim 11 is not obvious. Claim 23 is also not obvious over Richards for additional reasons.

Claim 23 recites that the first securing element and the second securing element are oriented at least substantially perpendicular to the holes in the tissue in the second position. The Office Action purports that Richards discloses this feature on page 3 but does not indicate any portion of Richards that discloses such a feature.

Similar to that discussed above regarding claim 11, the fastener heads (315, 316) do not rotate to a second, substantially perpendicular position when deployed in tissue. The heads (315, 316) are thus also not oriented at least substantially perpendicular to the holes in the tissue in the second position and cannot be so oriented even if one desired such an orientation.

Accordingly, for at least all of the aforementioned reasons, dependent claim 23 distinguishes over Richards and represents allowable subject matter.

C. Rejection of Claims 7-10, 18-21, and 41-44 Pursuant to 35 U.S.C. §103(a) Over Richards in view of McQuilkin

Claims 7-10, 18-21, and 41-44 are finally rejected pursuant to 35 U.S.C. §103(a) as being unpatentable over Richards in view of McQuilkin.

1. The Examiner's Rejection of Independent Claims 7 and 41

The Examiner relies on Richards (Figures 8-10 and col. 6, lines 6-64) to disclose the claimed invention but admits that Richards fails to disclose that at least one through hole formed in the first bioimplantable pledget has a minimum diameter greater than a maximum diameter of the suture, as required by claim 7. The Examiner also admits that Richards fails to disclose a second bioimplantable pledget having at least one through hole formed therein, the first pledget being spaced apart from the second pledget to receive tissue therebetween when the tissue fixation device is deployed, as required by claim 41. The Examiner thus relies on McQuilkin for these features, arguing on pages 5-6 of the Office Action that

> [i]t would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of McQuilkin et al., to include first and second bioimplantable pledgets as claimed with the suture or suture portions and securing elements of Richards et al., and it would have been obvious to modify the diameter of at least one through hole in the first pledget and/or the diameter of the suture or suture portions of Richards et al., so that the diameters are configured as claimed. Such modifications would allow the device of Richards et al. to be quickly positioned about tissue and to effectively clamp and/or support organ tissue without undue tissue damage, as exemplified in figures 10-12 of McQuilkin et al.

2. Claims 7 and 42 are Patentable Over Richards in View of McQuilkin

Independent claim 7 recites a tissue fixation device including a suture and first and second bioimplantable pledgets. The first pledget has at least one through hole formed therein having a minimum diameter greater than a maximum diameter of the suture, a first portion of the suture passing through the at least one through hole in the first pledget and a second portion of the suture configured to inhibit the second portion from passing through the at least one through hole in the first pledget. The second pledget has at least one through hole formed therein, the first pledget being spaced apart from the second pledget to receive tissue therebetween when the tissue fixation device is deployed. The tissue fixation device also includes a first bioimplantable securing element connected to a portion of the suture and being rotatable from a first orientation in which the securing element is oriented at least substantially parallel to the at least one through hole formed in the first pledget and the second pledget, to a second orientation in which the securing element is oriented at least substantially perpendicular to the at least one through hole in the second pledget. The suture, the first and second pledgets, and the first securing element are effective to fix adjacent layers of living tissue.

As mentioned above, the Examiner admits on page 5 of the Office Action that Richards fails to disclose a first bioimplantable pledget having at least one through hole formed therein having a minimum diameter greater than a maximum diameter of the suture. The Examiner thus suggests modifying Richards in two ways in view of Figures 1 and 13 of McQuilkin, reproduced below, showing holes (302, 304, 322, 324) in pledgets (30, 32). Office Action, p. 5-6. First, the Examiner is suggesting that the washer (40B) of Richards's Figure 8 embodiment, reproduced again below, be used with the surgical fastener (305) of Richards's Figure 10, reproduced again below, and second, that the hole in the washer (40B) and/or the diameter of the filament (310) be modified such that the hole in the washer (40B) has a minimum diameter greater than a diameter of the filament (310). *Id.*

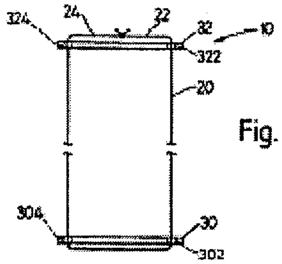

Fig. 1

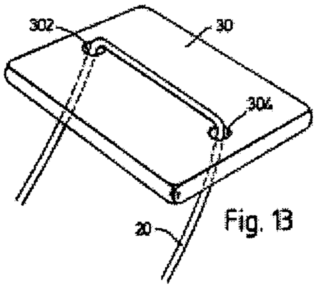

Fig. 13

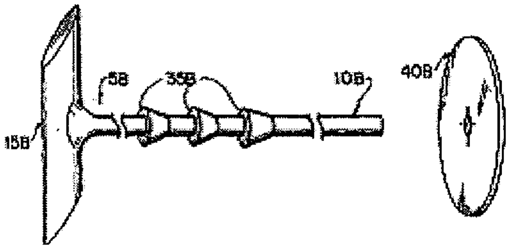

FIG. 8

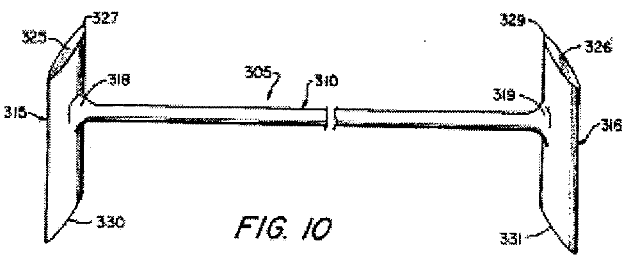

FIG. 10

The Examiner clarified in the Advisory Action dated May 21, 2009[1] that "one of ordinary skill in the art would not modify the washer 40B of Richards with holes each having a diameter greater than a maximum diameter of filament 40B, i.e., a filament or filament portion including ribs 35B." Instead, the Examiner is suggesting that Richards be modified in view of McQuilkin's teaching of

> a filament (without ribs) applied with washers, i.e., with securing elements, sutures, and a pledget (or washer) [and] the securement of tissue (without blind holes as taught by Richards), where securing elements, sutures (without ribs), and a plurality of pledgets are applicable. In other words, McQuilkin provides the teaching and motivation for modifying Richards' components for the securement of tissue, i.e., for the clamping and/or support of soft tissue with through-holes, where the soft tissue requires a plurality of pledgets for the prevention of undue tissue damage from sutures or filamentary securing elements (like Richards' fastener heads) engaged with the tissue.

Independent claim 7 distinguishes over Richards in view of McQuilkin at least because there is no motivation for a person of ordinary skill in the art to modify Richards in view of McQuilkin as proposed by the Examiner because not only is there no advantage or beneficial result to the proposed modification, the proposed modification would increase chances of harming tissue secured with Richards's surgical fastener.

(a) There Is No Motivation For A Person Of Ordinary Skill In The Art To Modify Richards To Have A First Pledget And A Suture Having The Required Dimensions

As mentioned above in discussing claim 11, the strongest rationale for combining references is a recognition that some advantage or expected beneficial result would be produced by the combination. MPEP §2144(II). Here, there is no advantage to or beneficial result in modifying Richards in view of McQuilkin as suggested by the Examiner, and in fact so modifying Richards's surgical fastener would be *disadvantageous* and *without benefit.*

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[1] The Advisory Action dated May 21, 2009 replied to Appellant's response to the Office Action dated March 12, 2009 rather than the most recent August 12, 2009 Office Action. However, the Office Actions dated March 12, 2009 and August 12, 2009 reject the same claims over the same art using the same analysis. The Examiner's analysis in the Advisory Action dated May 21, 2009 is thus relevant to the Office Action being appealed.

The only reason provided by the Examiner for any modification of Richards with McQuilkin is that the modification "would allow the device of Richards et al. to be quickly positioned about tissue and to effectively clamp and/or support organ tissue without undue tissue damage, as exemplified in figures 10-12 of McQuilkin et al." Office Action, p. 6. However, as discussed above regarding claim 11, the fasteners in Richards *already* effectively secure tissue, thereby making any modification of Richards in view of McQuilkin unnecessary and not obvious to a person having ordinary skill in the art.

More particularly regarding claim 7, if the washer (40B) of Richards's Figure 8 embodiment was used with its Figure 10 embodiment, as suggested by the Examiner, with the hole in the washer (40B) and/or the diameter of the filament (310) modified as proposed by the Examiner to have the dimensions required by claim 7, the washer (40B) would simply slide along the filament (310) without being effective for anything because the hole in the washer (40B) would be larger than a maximum diameter of the filament (310). In such a case, the washer (40B) would serve no purpose when the surgical fastener (305) is applied to tissue and would simply freely slide between the fastener heads (315, 316). The whole point of Richards providing the washer (40B) is so the washer (40B) can "catch" on one of the filament's ribs (35B) to secure the surgical fastener to tissue. Richards explicitly discloses that to be effective the hole in the washer (40B) purposely has a minimum diameter that is *less than* a maximum diameter of the filament so the larger diameter filament can prevent movement of the washer (40B) in one direction. Richards, col. 6, lines 6-19. That is the *opposite* of what is required by claim 7. Hence, a person skilled in the art would not make the modification proposed by the Examiner because the washer (40B) would serve no purpose.

Moreover, modifying the washer (40B) and/or the filament (310) to have the dimensions required by claim 7 would cause the washer (40B) to be a dangerous hindrance that would increase chances of tissue damage and not allow securement of tissue "without undue tissue damage" as argued by the Examiner. Office Action, p. 6. The washer (40B) would freely slide along the filament (310) outside the tissue anchored by the surgical fastener, or the washer (40B) would be disposed within the tissue on the filament as an extraneous piece of hardware. Either scenario increases chances of damaging tissue or otherwise harming the patient.

The Examiner's proposed modifications would similarly serve no purpose and increase chances of harming the patient if the fastener heads (315, 316) of Richards are not inserted in blind holes as shown, for example, in Figures 9, 12, and 13 of Richards, displayed above on pages 6 and 7. As discussed above, The Examiner appears to suggest in the Advisory Action dated May 21, 2009 that the proposed modification of Richards would allow the surgical fastener (310) of Richards to be used to secure tissue with the fastener heads (315, 316) being located outside tissue, such as shown with pledgets (30, 32) positioned outside tissue (50) in Figure 12 of McQuilkin, reproduced below. However, such use of the surgical fastener (310) would not be possible. Either the fastener heads (315, 316) would be positioned on opposite sides of the tissue (50), in which case the washer (40B) would be positioned uselessly and dangerously on the filament (310) extending through the tissue (50) between the heads (315, 316), or the heads (315, 316) would be on a same side of the tissue (50), in which case the washer (40B) would also be positioned uselessly and dangerously on the filament (310) along the filament (310) within the tissue (50) or be loose on the filament (310) outside the tissue (50). Simply put, without ribs on the filament (310), i.e., without the washer (40B) having a minimum diameter *less than* a maximum diameter of the filament with which it is used, there is no need for the washer (40B) to be used in conjunction with the filament regardless of any purported teachings of McQuilkin.

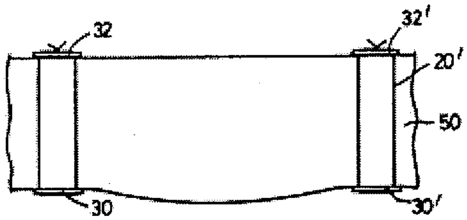

Fig. 12

Accordingly, since neither Richards nor McQuilkin provides any teachings that would offer any beneficial result to modifying the surgical fastener of Richards to have the recited dimensions as suggested by the Examiner, there is simply no advantage to so modify Richards. The modification is therefore not obvious and cannot form a basis on which to reject claim 7.

(b) There Is No Motivation For A Person Of Ordinary Skill In The Art To Modify Richards To Include Two Pledgets

The Examiner's rejection of claim 7 is also improper because there is no reason a person of ordinary skill in the art would modify Richards in view of McQuilkin such that Richards's surgical fastener includes first *and second* bioimplantable securing elements as also required by claim 7. Modifying the washer (40B) of Richards as suggested by the Examiner to have a plurality of through holes like the two holes formed in each of the pledgets (30, 32) in McQuilkin would serve no purpose.

McQuilkin's pledgets (30, 32) each have two holes to secure the pledgets (30, 32) together so they can fasten tissue. The suture (20) in McQuilkin is threaded through both holes (302, 304) in the bottom pledget (30), then through tissue (50), and then through both holes (322, 324) in the top pledget (32) to secure the pledgets (30, 32) together with the tissue (50) between the pledgets (30, 32). *See* McQuilkin, Figures 3-10; col. 1, line 65 to col. 2, line 12. In contrast, in Richards, a tissue fastener either has a filament extending between a head and a washer (Figure 8) or between two heads (Figure 10) to secure tissue therebetween. There is simply no need for the washer in Richards to be modified to have a plurality of through holes, much less for a *second* washer to be added, as suggested by the Examiner. The fasteners in Richards are perfectly effective for quick positioning about tissue and to clamp and/or support organ tissue without undue tissue damage. Indeed, Richards as disclosed would damage tissue *less* than Richards modified as suggested by the Examiner because Richards only uses a single length of filament inserted through tissue but the proposed modification would require multiple lengths of filament inserted through tissue.

Accordingly, since neither Richards nor McQuilkin provides any teachings that would offer any beneficial result to modifying the surgical fastener of Richards to have two bioimplantable pledgets as suggested by the Examiner, there is simply no advantage to so modify Richards. The modification is therefore not obvious and cannot form a basis on which to reject claim 7.

Accordingly, for at least these reasons, independent claim 7, as well as claim 42 which depends therefrom, distinguish over Richards and McQuilkin, alone or together, and represent allowable subject matter.

3. Claims 8 and 43 are Patentable Over Richards in view of McQuilkin

Claims 8 and 43 ultimately depend from claim 7. Accordingly, claims 8 and 43 are not obvious over Richards and McQuilkin for at least the same reasons that claim 7 is not obvious. Claims 8 and 43 are also not obvious over Richards and McQuilkin for additional reasons.

Claim 8 depends from claim 7 and recites a second suture and a second bioimplantable securing element connected to a portion of the second suture. The Examiner relies on column 6, lines 20-22 for disclosing a second suture (310). Office Action, p. 5.

Because claim 8 depends from claim 7, claim 8 hence requires a second suture in the device of claims 1 and 7. The surgical fastener (5B) embodiment of Richards's Figures 8 and 9 and the surgical fastener (310) embodiment of Richards's Figure 10 each clearly only include *one* filament. There is no teaching or suggestion in Richards for a surgical fastener to include first *and second* sutures.

McQuilkin is relied on for various features of other claims and fails to remedy the deficiencies of Richards as McQuilkin also fails to disclose a second suture, much less a second bioimplantable securing element connected to a portion of the second suture.

Accordingly, for at least all of the aforementioned reasons, dependent claim 8, as well as claim 43 which depends therefrom, distinguish over Richards and McQuilkin, alone or together, and represent allowable subject matter.

4. Claims 9 and 10 are Patentable Over Richards in view of McQuilkin

Claims 9 and 10 ultimately depend from claim 7. Accordingly, claims 9 and 10 are not obvious over Richards and McQuilkin for at least the same reasons that claim 7 is not obvious. Claims 9 and 10 are also not obvious over Richards and McQuilkin for additional reasons.

Claim 9 depends from claim 8, which depends from claim 7, and recites that a first portion of the second suture passes through a second through hole in the first pledget and a second portion of the suture is configured to inhibit the second portion of the suture from passing through the second through hole in the first pledget. The Examiner admits on page 5 of the Office Action that Richards fails to disclose that "a first portion of the second suture passes through a second through hole in the first pledget" and thus relies on McQuilkin for that feature, arguing that McQuilkin discloses a pledget "including a plurality of through holes (302, 304) for receiving first and second suture portions or ends (24, 22)." The Examiner fails to particularly address the recitation in claim 9 that a second portion of the suture is configured to inhibit the second portion of the suture from passing through the second through hole in the first pledget.

The Examiner's rejection is improper at least because, as discussed above regarding claim 8, neither Richards nor McQuilkin disclose first *and second* sutures. There is also no teaching or suggestion in McQuilkin that a second portion of the second suture is configured to *inhibit* the second portion of the second suture from passing through the second through hole in the first pledget. Conversely, in McQuilkin the one suture (20) is freely passable through the holes (302, 304). Thus, even if the references were combined as suggested by the Examiner, the claimed invention would still not result at least because a first portion of a *second suture* would not pass through a second through hole of a first pledget and because a second portion of the second suture is configured to *inhibit* the second portion of the second suture from passing through the second through hole in the first pledget.

Accordingly, for at least all of the aforementioned reasons, dependent claim 9, as well as claim 10 which depends therefrom, distinguish over Richards and McQuilkin, alone or together, and represent allowable subject matter.

5. *Claims 18-21 are Patentable Over Richards in View of McQuilkin*

Claims 18-21 ultimately depend from claim 11. Accordingly, claims 18-21 are not obvious over Richards for at least the same reasons that claim 11 is not obvious. McQuilkin fails to remedy the deficiencies of Richards at least because as discussed above Richards would not be modified by a person of ordinary skill in the art as suggested by the Examiner, and McQuilkin fails to provide any motivation for such a modification.

Accordingly, for at least all of the aforementioned reasons, dependent claims 18-21 distinguish over Richards and McQuilkin, alone or together, and represent allowable subject matter.

6. Claims 41 and 44 are Patentable Over Richards in View of McQuilkin

Independent claim 41 recites a tissue fixation device including a suture and first and second bioimplantable pledgets. The first pledget has a plurality of through holes formed therein, the suture passing through the through holes. The second pledget has a plurality of through holes formed therein, the first pledget being spaced apart from the second pledget to receive tissue therebetween when the tissue fixation device is deployed. The tissue fixation device also includes a first bioimplantable securing element being coupled to the suture and having a sharp tip and a proximal end configured for removable attachment to an instrument, and a second bioimplantable securing element being coupled to the suture and having a sharp tip and a proximal end configured for removable attachment to an instrument. The suture, the first and second pledgets, and the first and second securing elements are effective to fix adjacent layers of living tissue.

As mentioned above, the Examiner admits on page 5 of the Office Action that Richards fails to disclose a second bioimplantable pledget and first and second pledgets each having a plurality of through holes. The Examiner thus suggests modifying Richards in view of McQuilkin's disclosure of first and second bioimplantable pledgets (30, 32) each having two through holes (302, 304).

The only reason provided by the Examiner for modifying Richards in view of McQuilkin is that the modification "would allow the device of Richards et al. to be quickly positioned about tissue and to effectively clamp and/or support organ tissue without undue tissue damage, as exemplified in figures 10-12 of McQuilkin et al." Office Action, p. 6. However, as discussed above regarding claims 7 and 11, the fasteners in Richards *already* achieve this result, thereby making any modification of Richards in view of McQuilkin unnecessary and not obvious to a person having ordinary skill in the art.

As also discussed above regarding claim 7, there is no motivation for a person of ordinary skill in the art to include a second pledget in Richards as required by claim 41.

Accordingly, for at least these reasons, independent claim 41, as well as claim 44 which depends therefrom, distinguish over Richards and McQuilkin, alone or together, and represent allowable subject matter.

D. Rejection of Claims 16, 17, 27, and 28 Pursuant to 35 U.S.C. §103(a) Over Richards in view of Bonutti

Claims 16, 17, 27, and 28 are finally rejected pursuant to 35 U.S.C. §103(a) as being unpatentable over Richards in view of Bonutti. Claims 16, 17, 27, and 28 ultimately depend from claim 11. Accordingly, claims 16, 17, 27, and 28 are not obvious over Richards for at least the same reasons that claim 11 is not obvious. Bonutti fails to remedy the deficiencies of Richards at least because as discussed above Richards would not be modified by a person of ordinary skill in the art as suggested by the Examiner, and Bonutti fails to provide any motivation for such a modification. Claims 27 and 28 are also not obvious over Richards and Bonutti for additional reasons.

1. Claim 27 is Patentable Over Richards in view of Bonutti

Claim 27 depends from claim 11 and recites that the suture is endless. The Examiner admits that Richards fails to disclose such a feature and thus relies on Bonutti for this recitation.

The Examiner does not particularly address where Bonutti discloses a suture that is endless but generally refers to Figure 6, reproduced below, and column 3, lines 22-29 in rejecting claim 27 on page 6 of the Office Action. However, neither of these portions, nor any other portion of Bonutti, provide any teaching or suggestion of a suture that is endless. In fact, Bonutti indicates the *opposite*, that its suture is *not* endless. Column 3, lines 22-29 of Bonutti's specification states that the suture (12) has inner and outer legs (48, 50) that "*extend to a remote location* (not shown) which is offset to one side of the body tissue 14." (Emphasis added.) In addition to Figure 6 clearly showing free ends of the legs (48, 50) near the reference numerals 48 and 50, there is absolutely no indication in Bonutti that the inner and outer legs (48, 50) are coupled together at the non-illustrated remote location such that the suture 12 is endless. Moreover, by indicating that the suture 12 has *legs*, Bonutti implies that the suture 12 has free ends because a "leg" as set forth in a

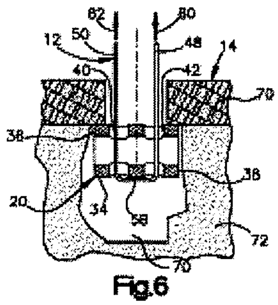

Fig.6

dictionary and as generally understood indicates a side of an object connected to something at one end and free at the other end. *See, e.g., Dictionary.com Unabridged*, accessed October 15, 2009 (providing contextually appropriate definitions of "leg" as "something resembling or suggesting a leg in use, position, or appearance" and "one of the sides of a forked object, as of a compass or pair of dividers").

Bonutti fails to disclose a suture that is endless, and it is impermissible for the Examiner to import such a feature into Bonutti, seemingly only to formulate a rejection of the claim. Even if Richards and Bonutti were combined as suggested by the Examiner, the claimed invention would simply not result. The Examiner has thus failed to establish a prima facie case of obviousness regarding claim 27.

Accordingly, for at least all of the aforementioned reasons, dependent claim 27 distinguishes over Richards and Bonutti, alone or together, and represents allowable subject matter.

2. Claim 28 is Patentable Over Richards in view of Bonutti

Claim 28 depends from claim 11 and recites that the suture forms a closed loop. The Examiner admits that Richards fails to disclose such a feature and thus relies on Bonutti for this feature.

The Examiner does not particularly address where Bonutti discloses a suture that forms a closed loop but generally refers to Figure 6, reproduced below, and column 3, lines 22-29 in rejecting claim 27 on page 6 of the Office Action. However, as discussed above regarding claim 27, Bonutti only discloses a suture 12 having inner and outer legs 48, 50 that by all indications are unconnected portions of the suture 12. Bonutti simply fails to disclose a suture that forms a *closed loop*, and it is impermissible for the Examiner to import such a feature into Bonutti, seemingly only to formulate a rejection of the claims. Even if Richards and Bonutti were combined as suggested by the Examiner, the claimed invention would simply not result. The Examiner has thus failed to establish a prima facie case of obviousness regarding claim 28.

Accordingly, for at least all of the aforementioned reasons, dependent claim 28 distinguishes over Richards and Bonutti, alone or together, and represents allowable subject matter.

VIII. CONCLUSION

For the reasons noted above, Appellant submits that the pending claims define patentable subject matter. Accordingly, Appellant requests that the Examiner's rejection of these claims be reversed and that the pending application be passed to issue.

Respectfully submitted,

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APPENDIX A: CLAIMS ON APPEAL

1-6. (Canceled).

7. (Previously Presented) A tissue fixation device comprising:

a suture;

a first bioimplantable pledget having at least one through hole formed therein having a minimum diameter greater than a maximum diameter of the suture, a first portion of the suture passing through the at least one through hole in the first pledget and a second portion of the suture configured to inhibit the second portion from passing through the at least one through hole in the first pledget;

a second bioimplantable pledget having at least one through hole formed therein, the first pledget being spaced apart from the second pledget to receive tissue therebetween when the tissue fixation device is deployed;

a first bioimplantable securing element connected to a portion of the suture, the first securing element being rotatable from

a first orientation in which the securing element is oriented at least substantially parallel to the at least one through hole formed in the first pledget and the second pledget, to

a second orientation in which the securing element is oriented at least substantially perpendicular to the at least one through hole in the second pledget,

wherein the suture, the first and second pledgets, and the first securing element are effective to fix adjacent layers of living tissue.

8. (Previously Presented) The tissue fixation device of claim 7, further comprising a second suture and a second bioimplantable securing element connected to a portion of the second suture.

9. (Original) The tissue fixation device of claim 8, wherein a first portion of the second suture passes through a second through hole in the first pledget and a second portion of the suture is configured to inhibit the second portion of the suture from passing through the second through hole in the first pledget.

10. (Original) The tissue fixation device of claim 9, wherein the second securing element is rotatable from

a first position in which the second securing element is oriented at least substantially parallel to the second through hole in the first pledget and a second through hole in the second pledget to

a second position in which the securing element is oriented at least substantially perpendicular to the second through hole in the second pledget.

11. (Previously Presented) A tissue fixation device comprising:

a suture suitable for in vivo placement in a human body;

a first biocompatible securing element connected to a first portion of the suture;

a second biocompatible securing element connected to a second portion of the suture, each said first and second securing elements being rotatable from a first position during deployment of the tissue fixation device that is suitable for each securing element to pass through a respective hole formed in human or animal tissue to a second position substantially perpendicular to the first position when the tissue fixation device is deployed that inhibits each securing element from passing through the respective hole formed in said tissue; and

a deployment instrument having first and second tubes configured to deliver the first and second securing elements in the first position through the tubes and through the respective hole formed in said tissue.

12. (Previously Presented) The tissue fixation device of claim 11, wherein the first and second securing elements are spaced apart from a third portion of the suture when the tissue fixation device is deployed, the human or animal tissue being fixed between the securing elements and the third portion during deployment.

13. (Original) The tissue fixation device of claim 12, wherein a portion of the suture is coupled to another portion of the suture.

14. (Original) The tissue fixation device of claim 13, wherein the portions are coupled by knotting.

15. (Original) The tissue fixation device of claim 13, wherein the portions are coupled by welding.

16. (Original) The tissue fixation device of claim 13, wherein the first portion of the suture passes through openings in the first securing element.

17. (Original) The tissue fixation device of claim 16, wherein the second portion of the suture passes through openings in the second securing element.

18. (Original) The tissue fixation device of claim 11, further comprising a first pledget having a plurality of through holes formed therein, the suture passing through the through holes in the first pledget.

19. (Original) The tissue fixation device of claim 18, further comprising a second pledget having a plurality of through holes formed therein, the suture passing through the through holes in the second pledget, the second pledget being spaced apart from the first pledget when the tissue fixation device is deployed.

20. (Original) The tissue fixation device of claim 18, wherein the suture passes through the through holes as to enable the pledget to be positioned between the first and second securing elements and the tissue when the tissue fixation device is deployed.

21. (Original) The tissue fixation device of claim 18, wherein the suture has two ends, and both ends are disposed on the same side of the first pledget.

22. (Original) The tissue fixation device of claim 11, wherein the first securing element and the second securing element are oriented at least substantially parallel to the holes in the tissue in the first position.

23. (Original) The tissue fixation device of claim 11, wherein the first securing element and the second securing element are oriented at least substantially perpendicular to the holes in the tissue in the second position.

24. (Original) The tissue fixation device of claim 11, wherein the first securing element and the second securing element are each generally cylindrical in shape.

25. (Original) The tissue fixation device of claim 11, wherein each said first securing element and second securing element includes a sharp tip.

26. (Original) The tissue fixation device of claim 11, wherein each said first securing element and second securing element have an elongated shape such that the long axis of the securing element is larger than the diameter of the respective hole.

27. (Original) The tissue fixation device of claim 11, wherein the suture is endless.

28. (Original) The tissue fixation device of claim 11, wherein the suture forms a closed loop.

29-40. (Cancelled).

41. (Previously Presented) A tissue fixation device comprising:

a suture;

a first bioimplantable pledget having a plurality of through holes formed therein, the suture passing through the through holes in the first pledget;

a second bioimplantable pledget having a plurality of through holes formed therein, the first pledget being spaced apart from the second pledget to receive tissue therebetween when the tissue fixation device is deployed;

a first bioimplantable securing element having a sharp tip and a proximal end configured for removable attachment to an instrument, the first securing element being coupled to the suture; and

a second bioimplantable securing element having a sharp tip and a proximal end configured for removable attachment to an instrument, the second securing element being coupled to the suture,

wherein the suture, the first and second pledgets, and the first and second securing elements are effective to fix adjacent layers of living tissue.

42. (Previously Presented) The tissue fixation device of claim 7, wherein said suture comprises a material suitable for suturing human or animal tissue in vivo, and

said securing element comprises biocompatible material.

43. (Previously Presented) The tissue fixation device of claim 8, wherein said second suture comprises a material suitable for suturing human or animal tissue in vivo, and

said second securing element comprises biocompatible material.

44. (Previously Presented) The tissue fixation device of claim 41, wherein said suture comprises a material suitable for suturing human or animal tissue in vivo, and

said first and second securing elements comprise biocompatible material.

APPENDIX B: EVIDENCE

Attached: Patent Assignment assigning rights in the present application from NDO Surgical, Inc. to Ethicon Endo-Surgery, Inc.

APPENDIX C: RELATED PROCEEDINGS

No related proceedings.